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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/501,773

Filing Date: July 20, 2004

Appellant(s): KOLTER ET AL.

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Michael P. Byrne  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 5/22/2008 appealing from the Office action mailed 12/10/2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

WO 00/18375	Gotsche et al.	4-2000
US 5,091,185	Castillo et al.	2-1992
US 4,842,854	Babaian et al.	6-1989

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

Claims 1, 2, 5, 10, 20, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gotsche (WO/00/18375) (Page: Lines: 1:5-12, 4:3-11, 19:10-34, Example 7).

In reference to claim 1, Gotsche discloses a coating agent, binder or film-forming excipient composition for solid substrates. Wherein the composition is comprised of Component A: a graft copolymer of polyvinyl alcohol and polyether (formed via polymerization of one vinyl ester of aliphatic C<sub>1</sub>-C<sub>24</sub> carboxylic acids in the presence of a polyether), and Component B: an additional polymer.

It is noted that applicants recognize that the herein claimed polyvinyl alcohol-polyether graft copolymer is obtained by polymerizing (a) at least on vinyl ester of aliphatic C<sub>1</sub>-C<sub>24</sub> carboxylic acids in the presence of a polyether (Herein applicant's specification PG PUB see [0010-0012]). Thus, Component A is clearly disclosed by Gotsche.

In reference to component B, Gotsche discloses that the graft copolymer can be combined with additional polymers, wherein the ratio of the graft copolymer to the additional polymer is 1:9 to 9:1. The examiner recognizes that Gotsche discloses, as an alternate embodiment, the inclusion of the additional polymer; as per MPEP § 2123, alternate embodiments constitute prior art. As discussed above, the reference anticipates the claimed graft copolymer species, thus anticipates, in an alternate embodiment, the claimed invention.

In reference to claims 2, 5, and 10, component B is a polymer; suitable compounds include the elected species of polyvinyl alcohols, polyvinylpyrrolidones and polyvinylpyrrolidone copolymers.

In reference to claim 20, regarding component C, Gotsche discloses that the graft copolymer can be applied in pure form or else together with conventional excipients to the substrate, including colored pigments, wherein the weight percentage of the conventional excipients in the composition is exemplified as 3 wt %.

In reference to claim 27-28, Gotsche discloses that solid substrates can be coated with the coating agent disclosed above. Additionally, the substrate can be a pharmaceutical formulation, such as tablets.

Claim Rejections - 35 USC § 103

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotsche as applied to claim 1 above, and further in view of Castillo (US 5091185).

Gotsche fails to disclose that component B is a polyvinyl alcohol having a degree of hydrolysis of between 80 and 90 mol%. Hence attention is directed towards the Castillo reference, which discloses solid pellets of the biologically active materials coated with a composition comprising polyvinyl alcohol (PVA), wherein the polycinyl alcohol preferably has a degree of hydrolysis greater than about 95% (col. 2, lines 35-55). Gotsche and Castillo are analogous art because they are from a similar problem solving area, coating solid pharmaceutical materials. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to replace Component B of Gotsche with the hydrolyzed PVA of Castillo. The motivation to do so, as taught by Castillo, is employ the hydrolyzed PVA in order to effectively control the release of the active

material after implantation to provide a more uniform rate of delivery over a longer period of time as compared to uncoated pellets (col. 2, lines 35-55).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotsche (WO/00/18375) as applied to the claims above, and further in view of Babaian et al. (US 4842854).

Gotsche fails to disclose that component B comprises vinylpyrrolidone-(meth)acrylate copolymers. Thus attention is directed towards the Babaian reference, which is drawn to pharmaceutical film composition. The film of Babaian comprises vinylpyrrolidone, or a copolymer thereof with an acrylate, wherein the film is recognized as a biologically soluble and resolvable carrier. Specifically, the disclosed film is mouth mucosa soluble, swellable and resolvable polymeric film-forming carrier (col. 16, line 61 to col. 17, line 4; claim 1).

It is noted that, for component B, Gotsche discloses that suitable film formers include polyvinylpyrrolidone and polyvinylpyrrolidone copolymers. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize vinylpyrrolidone-acrylate copolymer as component B in the invention of Gotsche, as taught by Babaian. The motivation includes utilization of a mouth mucosa soluble, swellable and resolvable polymeric film-forming carrier.

Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotsche (WO/00/18375).

Gotsche applies as above, however, fails to disclose that component C is present in at least 5 wt % of the composition. It is noted that Gotsche exemplifies the weight percentage of the conventional excipients (component C) in the composition as 3 wt % (Example 7 and 8). However, Gotsche discloses that the examples of conventional excipients include white pigments such as

titanium dioxide which increase the hiding power, in addition to mentioning other suitable excipients and their advantages (page 19, lines 10-21). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to increase the amount of any of the conventional excipients mentioned by Gotsche in order increase the respective advantages, such as increase the hiding power, increase non-sticking, or to further improve the wetting characteristics. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

#### **(10) Response to Argument**

Appellants have argued that the Gotsche fails to anticipate the claimed invention, because in order to arrive at the claimed invention appellants have to select component A, select component B, and then combine components A and B.

In response, in reference to component A, appellant has claimed the genus polyvinyl alcohol-polyether graft copolymer, wherein the reference discloses a graft copolymer genus of polyvinyl alcohol and polyether (Gotsche at page 3, line 42 to page 5, line 10). The reference discloses formation of the copolymer via polymerization of the same exact components as disclosed by appellant in the instant specification (PG PUG of the instant application at [0010-0012]). Furthermore, given that appellant has claimed a genus and the reference has disclosed the genus, the component is anticipated and species selection is not required for component A.

In reference to component B, appellant has claimed an additional polymer with at least one of the claimed functional groups (component B), wherein the reference discloses the claimed additional polymers within a listing of eleven species (Gotsche at page 19, lines 22-34).

It is noted that three of the eleven disclosed species in the prior art read on the species claimed in the instant dependent claims. The limited class of 11 compounds, three of which are claimed (claims 5 and 10) is considered anticipation because one skilled in the art would readily envisage each member of the limited class. Thus, given that the reference clearly names the more than one of the claimed species, component B is anticipated.

Appellants have argued that it is necessary to select portions of the teaching within a reference and combine, thus, appellants argue, the claims are not anticipated by the prior art Gotsche. In response, Gotsche discloses as an alternate embodiment the inclusion of additional polymers (Component B), wherein as per MPEP § 2123, alternate embodiments constitute prior art. Thus, it is clear that the Gotsche reference discloses the claimed invention as arranged in the claim.

In reference to the 103(a) rejection of claim 7, appellant has argued that no teaching, suggestion, or motivation exists to combine the references. In support of their argument, appellants have stated that Gotsche is drawn to coatings with the instant release of the active material, wherein the Castillo reference is drawn to extended release coatings. The examiner has thoroughly considered the arguments and support provided, and concludes that the rejection is valid. The invention of Gotsche is drawn to a coating agent, binder and/or film-forming excipient in pharmaceutical presentations (1:2-4). Although, Gotsche discusses the instant release of the active material, the reference teaches that the rate of release of the active ingredient can be adjusted by the film coating (1:19-21). Thus, Gotsche teaches modification of the rate of release and the Castillo reference, as discussed in the rejection above, teaches a specific component utilized to control the rate of release of a film coating on a pharmaceutical presentation.



Appellants have argued that Castillo reduces the rate of release, however, the col. 5, lines 29-38 of Castillo indicate that a fully hydrolyzed polymer has a high degree of water resistance and dissolve very slowly at particular temperatures. Thus, it is clear that a fully hydrolyzed polymer will indeed reduce the rate of release, but clearly, it teaches that polymers less than 100% hydrolyzed will result in a increase in the rate of release. Appellants argument regarding the claim limitation "quick dissolving" release is not of substantial weight given that appellants have failed to claim what exactly defines "quick dissolving." Furthermore, this limitation is considered an inherent property of the claimed invention, wherein given that the prior art discloses the claimed composition in the claimed amounts it is inherent that that the composition will be rendered "quick dissolving."

Appellant has argued that the instant specification discloses synergistic effects unforeseen by the Gotsche reference. In response, as per MPEP § 2131.01, evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to 35 U.S.C. 102 rejections and thus cannot overcome a rejection so based. In re Wiggins, 488 F.2d 538, 543, 179 USPQ 421, 425 (CCPA 1973). Thus, the results cannot overcome the 102(b) rejection. Further, the results are insufficient to overcome the 103 rejections because the evidence fails to overcome the basis of the prima facie case of obviousness. The prima facie case of obviousness is based on utilizing hydrolyzed PVA; however appellants' evidence is based on the combination of components A and B. The primary reference anticipates the combination of components A and B, thus the showing is insufficient to overcome the prima facie case of obviousness. Attention is directed to MPEP § 716.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Art Unit: 1796

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Saira Haider/

Examiner, Art Unit 1796

Saira B. Haider

Conferees:

/James J. Seidleck/

Supervisory Patent Examiner, Art Unit 1796

/Gregory Mills/

TQAS TC 1700